510(k) Summary

Submitter: IDev Technologies, Inc.
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Contact Person: Mrs. Shannon Hurd
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Date Prepared: April 12, 2005

Trade Name: Texan LONGhorn™ Foreign Body Retrieval Device

Common Name: Snare

Classification Name: Catheter, Embolectomy (21 CFR 870.5150)

Product Code: DXE

Predicate Device: Texan™ Foreign Body Retrieval Device

Device Description:

The Texan LONGhorn™ is comprised of the following:

- A nitinol wire formed into a loop. The wire is secured distally to the catheter body; the proximal wire end is attached to a shaft that functions as a push-rod, and passes through a catheter. The "loop" portion of the wire has a platinum core for enhanced radiopacity.
- An inner member accepting an 0.018" guidewire. The proximal end of the inner carrier extends out the side port of a Y-connector allowing for the physician to manipulate the guidewire thru the device.
- An outer member. The proximal end is connected to a hemostasis Y-connector, having a side port and Tuohy-Borst connector on the central port for securing the hypotube.
    - the Tuohy-Borst connector allows the physician to secure the loop size once it is deployed to the desired diameter
    - the side port of the Y-connector allows access to the guidewire-dedicated lumen and the T-connector to allow for contrast injection and flushing

The loop is activated by moving the red capped knob and handle axially. The device should be manipulated in such a way that the loop can surround the foreign body. To capture the foreign body, the user shall slowly tighten the loop around the foreign body by retracting the red capped knob proximally while the device is held stationary in position. Once the loop is tightened around the foreign body, the handle and shaft shall be locked by rotating the hemeostasis valve connected to the proximal end of the handle clockwise. Retrieval of the foreign body is performed by slowly withdrawing the Texan LONGhorn™ TX30120060 and the foreign body as a unit into the sheath.

Intended Use:
The Texan LONGhorn™ is intended for use as a tool to retrieve and manipulate foreign bodies from distal peripheral vessels of the cardiovascular system.

Technological Characteristics Compared to Predicate:
IDev Technologies, Inc. considers the Texan LONGhorn™ TX30120060 Foreign Body Retrieval Device as substantially equivalent to IDev's Texan™ TX30060050 Foreign Body Retrieval Device as listed in the following:

- Indication for Use
- Loop
  - *Material*
  - *Radiopacity*
  - *Orientation*
  - *Torque Control/Steerability*
  - *Guidewire Compatibility*
  - *Shaft Reinforcement*
  - *Loop Size*
  - *Adjustability*
  - *Contract Injectability Catheter*
- Function
  - *Advancement*
  - *Catheter Advancement*
  - *Loop Usage*

Non-clinical Performance Testing:
The Texan LONGhorn™ Foreign Body Retrieval Device has successfully passed all functional and safety testing requirements to ensure substantial equivalence to the predicate device. The testing is described below:

- Tensile - to verify design meets minimum tensile strength requirements at all joints, as defined in product specification.
- Animal Study - to evaluate the safety and efficacy of a proposed device, and evaluate operational characteristics of the device with respect to utilization of a predicate device.

Conclusion:
IDev Technologies, Inc. considers the Texan LONGhorn™ Foreign Body Retrieval Device to be substantially equivalent to the Texan™ Foreign Body Retrieval Device based on design and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2005

IVed Technologies, Inc.
c/o Ms. Shannon Hurd
Quality Manager
1110 Nasa Parkway, Suite 311
Houston, TX 77058

Re: K050926
Trade Name: Texan LONGhorn™
Regulation Number: 21 CFR 870.3460
Regulation Name: Embolectomy Catheter
Regulatory Class: II (two)
Product Code: MMX
Dated: April 12, 2005
Received: April 15, 2005

Dear Ms. Hurd

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050926

Indications for Use

510(k) Number (if known):

Device Name: **Texan LONGhorn™ Foreign Body Retrieval Device**

Indications For Use: **The Texan LONGhorn™ Foreign Body Retrieval Device is intended for use as a tool to retrieve and manipulate foreign bodies from distal peripheral vessels of the cardiovascular system.**

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmes

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K050926